

10.22.02.00

# **Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

## **Subtitle 22 DEVELOPMENTAL DISABILITIES**

### **Chapter 02 Administrative Requirements for Licensees**

**Authority: Health-General Article, §§7-904 and 7-909, Annotated Code of Maryland**

10.22.02.01

#### **.01 Incorporation by Reference.**

The Developmental Disabilities Administration, Policy on Reportable Incidents and Investigations, (Effective Date: October 1, 2007, is incorporated by reference.

10.22.02.01-1

#### **.01-1 License Required.**

A. In addition to any other license required by law, a person shall be licensed by the Administration before the person may provide any of the following services to an individual with a developmental disability or to an individual eligible to receive individual support services:

- (1) Vocational and day services;
- (2) Community residential services;
- (3) Resource coordination;
- (4) More than one family support service, as defined in Health-General Article, §7-701, Annotated Code of Maryland;
- (5) More than one individual support service, as defined in Health-General Article, §7-706, Annotated Code of Maryland; and

(6) More than one community supported living arrangement service as defined in Health-General Article, §7-709, Annotated Code of Maryland.

B. Waiver. The Director may waive the requirement for a license if a person is licensed or certified by another State agency or accredited by a national accreditation agency, such as the Council on Quality and Leadership in Supports for People with Developmental Disabilities or the Council for Accreditation for Rehabilitation Facilities (CARF), to provide services to an individual with a developmental disability or to an individual eligible for individual support services.

C. After notice and an opportunity for a hearing, the Director may revoke the waiver granted under §B of this regulation if, through inspection, it is determined that a person is providing services which would not conform in substantial part to the licensing requirements of this subtitle.

D. A person who provides residential services to a child with a developmental disability shall meet the requirements of COMAR 14.31.05, 14.31.06, and 14.31.07, in addition to the requirements of this chapter.

10.22.02.02

## **.02 Application for Initial License or Renewal.**

A. To obtain and maintain a license, an applicant shall, at a minimum:

(1) Except for local health departments, be properly organized as a Maryland corporation, a forensic residential center (FRC), or a State residential center (SRC), or, if operating as a foreign corporation, be properly registered to do business in Maryland;

(2) Have a governing body that is legally responsible for overseeing the management and operation of all programs conducted by the licensee;

(3) Have a governing body that is legally responsible for ensuring that each aspect of the licensee's program operates in compliance with all of the requirements of this chapter and all other applicable laws and regulations; and

(4) Except for currently licensed providers, demonstrate the capability to provide or arrange for the provision of all applicable services required by this chapter by submitting, at a minimum, the following documents to the Department:

(a) A business plan that clearly demonstrates the ability of the applicant to provide services in accordance with this chapter;

- (b) A summary of the applicant's demonstrated experience in the field of developmental disabilities;
  - (c) Prior licensing reports issued within the previous 10 years from any in-State or out-of-State entity associated with the applicant, including deficiency reports and compliance records; and
  - (d) A written quality assurance plan approved by the Administration in accordance with Regulation .14 of this chapter; and
- (5) If currently licensed, produce, upon written request from the Administration, the document required under §A(4) of this regulation.

B. An applicant shall file an application for a license or license renewal on a form provided by the Administration. An existing licensee shall file an application for renewal at least 60 days before expiration of its existing license. The license does not expire until the Director takes an action under §D of this regulation and the time for seeking judicial review or any judicial stay of the final action expires.

C. The administrative head of the corporation or two of its officers, local health officer, or SRC director, shall submit the application.

D. When an application for initial licensure or renewal is submitted, the Director may:

- (1) Approve the application unconditionally and issue a license;
- (2) Approve the application with conditions and issue a license;
- (3) Deny the application for any reason including if an applicant has had a:
  - (a) License revoked by the Department within the previous 10 years; or
  - (b) Corporate officer who has served as a corporate officer for a licensee that has had a license revoked by the Department within the previous 10 years; or
- (4) Require additional information before a licensure decision is made.

E. Hearing Request.

- (1) If the Director proposes to deny a license under this section, the Director shall notify the applicant in writing of the proposed decision and inform the applicant of the reason for the proposed denial and the right to a hearing.
- (2) A request for a hearing, including a copy of the Director's action, shall be filed with the Office of Administrative Hearings with a copy to the Administration not later than 30 days after receiving notice of the Director's proposed action.

(3) A hearing requested under this chapter shall be conducted in accordance with State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland, and COMAR 28.02.01 and 10.01.03.

(4) The burden of proof is as set forth in COMAR 10.01.03.28.

(5) Unless otherwise stated in this chapter, the Office of Administrative Hearings shall issue a proposed decision within the time frames set forth in COMAR 28.02.01.

(6) The aggrieved person may file exceptions as set forth in COMAR 10.01.03.35.

(7) A final decision by the Secretary shall be issued in accordance with COMAR 10.01.03.35.

#### F. Voluntary Surrender of License.

(1) If a licensee intends to voluntarily surrender its license, the licensee shall submit a closure schedule which the Director shall approve before the surrender becomes effective.

(2) The licensee shall submit a schedule for closure to the Director, in writing, at least 90 days before surrendering its license.

(3) The Director may grant the requested closure schedule as submitted, or require the licensee to continue to operate for an additional 90 days to allow the Administration time to plan for the continued provision of services to the individuals served by the licensee.

(4) The Administration shall notify appropriate individuals and proponents of the licensee's intent to surrender its license and of the Director's approved closure schedule.

#### G. The licensee may terminate services to an individual for good cause only with the written approval of the Director. The licensee shall:

(1) Notify the Director in writing 90 days before the date it proposes to terminate services to an individual;

(2) Notify the individual, and proponent, when appropriate, in writing, of its intent to terminate services and the individual's right to a hearing under COMAR 10.22.16, within the same time frame set forth in §G(1) of this regulation, and provide copies of that notice at that time to the appropriate regional office and members of the individual's team; and

(3) Consider the service terminated, if an individual is absent from a service for 60 consecutive days, unless otherwise determined by the Director.

### **.03 Investigation by the Administration.**

A. This regulation sets forth the roles of the Developmental Disabilities Administration and the Office of Health Care Quality in investigation and follow-up of reportable incidents.

B. Licensee to be Open for Inspection. A licensee shall be open at all reasonable times to announced and unannounced inspections by the Administration or its designee.

C. Records and Reports. A licensee shall maintain records and make reports as required by the Administration. The records and reports shall be open to inspection by the Administration. A licensee shall immediately, on request of the Administration, provide copies of the records and reports, including medical records of individuals, to the Administration.

D. Protocol to Determine Necessity to Investigate.

(1) The Administration, through its agent, the Office of Health Care Quality (OHCQ), shall investigate reportable incidents, events, or problems involving individuals in a community agency or State residential center based on the scope and severity in accordance with the Developmental Disabilities Administration, Policy on Reportable Incidents and Investigations.

(2) The licensee shall report incidents in accordance with the requirements and timelines outlined in the Developmental Disabilities Administration, Policy on Reportable Incidents and Investigations.

(3) The necessity for investigation is determined by the following priorities:

(a) Priority Level 1—Immediate Jeopardy—Initiate investigation within 2 working days of receipt;

(b) Priority Level 2—High—Initiate investigation within 4 working days of receipt;

(c) Priority Level 3—Other Harm—Initiate an investigation within 30 working days of receipt;

(d) Priority Level 4—Administrative Review—Review during preparation for licensee's annual survey;

(e) Priority Level 5—Referrals—Refer to internal OHCQ unit or appropriate agency for follow-up within 1 working day; or

(f) Priority Level 6—Death—Upon notification, refer to the Mortality Review Unit of OHCQ within 1 working day for review and investigation.

(4) Timelines for Specific Reports and Follow-Up Protocols.

(a) The licensee shall submit a plan of correction (POC) within 10 working days of the receipt of deficiencies. The POC due date may be sooner than 10 working days when the nature of the

deficiency warrants a more immediate response, as determined by the OHCQ and as outlined in Appendix 6 of the Developmental Disabilities Administration, Policy on Reportable Incidents and Investigations.

(b) If the POC is determined to be acceptable, the OHCQ shall, whenever possible, within 10 working days of approving the POC, send the statement of deficiency and the POC to the:

(i) Licensee who is required to share this information with the individual receiving services, who is the specific subject of a deficient practice, or to the resource coordinator, a guardian, or a family member as appropriate and set forth in the Developmental Disabilities Administration, Policy on Reportable Incidents and Investigations;

(ii) Complainant;

(iii) Agency's Executive Director and Board President;

(iv) DDA Regional Office;

(v) Maryland Disability Law Center when required by Developmental Disabilities Administration Policy on Reportable Incidents and Investigations;

(vi) Medicaid Fraud Control Unit of the Attorney General's Office when required by Developmental Disabilities Administration Policy on Reportable Incidents and Investigations;  
and

(vii) Any other parties determined to be appropriate by OHCQ.

(c) If the POC is determined to be unacceptable, the OHCQ shall, whenever possible, notify the agency in writing within 5 working days of receipt of the issues which require further review and consideration. The licensee shall resubmit to OHCQ a revised POC within 5 working days from notification of an unacceptable POC.

(d) OHCQ shall conduct follow-up monitoring in accordance with Developmental Disabilities Administration Policy on Reportable Incidents and Investigations.

E. Methods of Investigation. OHCQ shall conduct investigations through:

(1) On-site inspections;

(2) Interviews; or

(3) Reviews of relevant records and documents.

F. The licensee and OHCQ may receive extensions of the time periods set forth in this regulation for good cause shown.

10.22.02.04

#### **.04 Compliance Monitoring.**

A. The Administration, through its agent, the Office of Health Care Quality (OHCQ), is responsible for monitoring and inspecting the Administration's licensees to ensure regulatory compliance.

B. The Administration shall conduct an on-site pre-licensure survey.

C. The Administration shall conduct announced and unannounced licensure visits at any time the Administration considers necessary, but at least annually, and provide the licensee with any notification of noncompliance.

D. The Administration shall conduct announced or unannounced complaint investigation visits at any time the Administration considers necessary and provide the licensee with notification of any noncompliance.

E. The licensee shall submit a plan of correction (POC) at the end of an exit conference, or within 10 working days of receipt of the findings of noncompliance. The POC due date may be sooner than 10 working days when the nature of the noncompliance warrants a more immediate response, as determined by the OHCQ. The Director of the OHCQ may grant an extension of not more than 30 days for the submission of the POC.

F. If a POC is deemed unacceptable by the OHCQ, the licensee shall resubmit a revised POC within 10 working days to the OHCQ for approval.

10.22.02.05

#### **.05 New Site, Site Closure, or Relocation.**

A. A licensee may not open, close, or relocate any site without approval of the Administration. If a licensee intends to open, close, or relocate any site, the licensee shall request approval from the Administration and submit documentation as required by the Administration at least 30 days before the date the licensee intends to make the change.

B. If a licensee is required to open, close, or relocate a site due to an emergency and the notice requirements set forth in §A of this regulation cannot be met, the licensee shall notify the regional director as soon as the change occurs. The regional director shall notify the OHCQ of this change. The OHCQ shall ensure that the change meets with its approval.

10.22.02.06

### **.06 Licensed Capacity.**

A. A license issued by the Administration shall include the number of individuals for whom the licensee is permitted to provide services.

B. A licensee may exceed its licensed capacity only if the Director:

- (1) Requests in writing that the licensee exceed its licensed capacity; or
- (2) Approves a written request from a licensee to exceed its licensed capacity.

C. A licensee shall include in its written request to exceed its licensed capacity:

- (1) The circumstances or reasons for the request;
- (2) The identity of all individuals involved; and
- (3) Documentation that all individuals involved have been informed of the plan to exceed licensed capacity.

D. Permission to exceed licensed capacity shall be:

- (1) Granted for not more than 60 days; and
- (2) Extended for not more than an additional 60 days.

10.22.02.07

### **.07 Individual Family Care (IFC).**

A. On the effective date of this chapter, a community residential licensee providing IFC services may not contract with an IFC care provider who has a contract with another community residential licensee who provides IFC services.

B. Notwithstanding §A of this regulation, an individual who is receiving services in an IFC home before the effective date of these regulations may continue to receive services in that home.

10.22.02.08

### **.08 Governing Body.**



A. A local health department's governing body is the governing body of the respective county as set forth in Health-General Article, Title 3, Subtitle 3, Annotated Code of Maryland.

B. Except for local health departments, forensic residential centers (FRCs), and State residential centers, the governing body of all licensees shall include, at a minimum, at least one individual with a developmental disability, one family member of an individual with a developmental disability, and an individual with experience in the field of developmental disabilities.

C. Except for local health departments, forensic residential centers (FRCs), and State residential centers, the governing body of all licensees shall adopt written bylaws which require the governing body to be legally responsible for:

- (1) Overseeing the management and operation of the licensee;
- (2) Ensuring that the licensee operates in compliance with all of the requirements of this chapter and all other applicable laws and regulations;
- (3) Approving a licensee's mission statement, long-range goals, policies, procedures, and budget;
- (4) Defining and prohibiting those circumstances which would create a financial or personal conflict of interest for members of the governing body, staff, care providers, volunteers, and members of the standing committee;
- (5) Ensuring that the licensee responds to all POCs in a timely manner;
- (6) Approving a licensee's program service plan and ensuring that its services are provided in accordance with the plan;
- (7) Ensuring that at least 75 percent of the governing body of a licensee shall be residents of the State or reside within a 100 mile radius of the administrative offices of the licensee, which shall be located in the State unless the licensee:
  - (a) Has established an Administration approved community-based advisory board or committee; and
  - (b) Receives an Administration approved waiver;
- (8) Ensuring that no employee of a licensee or immediate family member of an employee of a licensee may serve as a voting member of the governing body of the licensee unless:
  - (a) The employee receives services from the licensee; or
  - (b) The Administration approves the composition of the governing body through an innovative program services plan in accordance with Regulation .09 of this chapter; and

(9) Ensuring that by January 1, 2008, members of the governing body and employees of the licensee may not own property that is leased back to the licensee.

10.22.02.09

### **.09 Program Service Plan (PSP).**

A. To receive a license from the Administration under this chapter, the applicant shall develop and submit for approval, as part of its application, a PSP for each service it provides.

B. If the licensee makes a change in its PSP, the licensee shall submit its revised PSP for the Administration's approval before the implementation of the changes.

C. The administrative head of the licensee shall assure that the PSP is reviewed by its governing body and updated at least every 3 years.

D. The licensee shall comply with all provisions of its approved PSP.

E. Contents. The licensee shall ensure the PSP includes the following components:

(1) Rationale, which includes a discussion of the applicant's philosophy for the provision of services;

(2) Scope, which includes a discussion of the specific services to be provided;

(3) Staffing and training, which includes a description of the staff or care providers necessary to provide the services outlined in §E(2) of this regulation and a description of any additional training required by its staff other than provided in Regulation .11 of this chapter; and

(4) Setting and location, which includes a description of where the services are to be provided and the number of individuals expected to be served.

F. Innovative Program Service Plan Variance.

(1) If an applicant or licensee wants to provide services or supports through an alternative model not currently regulated by this subtitle, the applicant or licensee may submit a PSP and request approval from the Administration to provide services or supports through this alternative model.

(2) The Administration shall consider whether the proposed model meets the overall goals of the Administration and reflects the values and outcomes delineated in COMAR 10.22.04.

(3) The Administration may approve the proposed model, as proposed, or with conditions, including which regulatory requirements of this subtitle would apply.

## **.10 Policies and Procedures.**

A. A licensee shall develop and adopt written policies and procedures for ensuring:

- (1) That each individual's health and safety needs, as identified in the individual plan (IP), are being met;
- (2) Fundamental rights in accordance with Health-General Article, §7-1002, Annotated Code of Maryland;
- (3) That services are provided in a manner which promotes individual choice and the exercise of individual rights;
- (4) Confidentiality for each individual in accordance with Health-General Article, §7-1010, Annotated Code of Maryland;
- (5) The implementation of a grievance process with safeguards which protect against retaliatory actions for the filing of any grievance;
- (6) That services are provided without discrimination;
- (7) That all incidents, including those involving life-threatening conditions, are reported and investigated in accordance with the Administration's procedures on reportable incidents;
- (8) That medications are administered in accordance with the practices established by the Administration's curriculum on medication training;
- (9) Compliance with COMAR 10.27.11;
- (10) That an individual whose behavior requires intervention receives the safeguards required by this regulation;
- (11) That in order for an individual to be required to pay for property damage caused by the individual's actions, the individual's IP shall show evidence that the:
  - (a) Individual has a history of destructive behavior that has been documented in the behavior plan (BP),
  - (b) Individual has a BP that addresses the destructive behavior,
  - (c) Individual has the ability to pay for damages,

(d) Licensee's standing committee, as described in Regulation .08 of this chapter, has reviewed and approved the damage payment, and

(e) Licensee has reported this approval to the regional director;

(12) Compliance with Health-General Article, §5-605, Annotated Code of Maryland;

(13) That there is no financial or personal conflict of interest for members of the governing body, staff, care providers, volunteers, and standing committee members;

(14) That the fiscal affairs of the licensee are conducted in accordance with generally accepted accounting practices;

(15) That there is adequate protection for the finances and property of each individual, including:

(a) A system to ensure that each individual's funds are used in an appropriate manner consistent with the individual's needs and preferences,

(b) A system to keep personal funds separate from the funds of the licensee and to ensure that funds are transferred to the individual in a timely manner when services are no longer being provided,

(c) Timely access for the individual to the funds,

(d) An accounting of the individual's funds, on request, and

(e) The accrual of any interest into the individual's account from an interest-bearing account;

(16) That State and federally required safety precautions, infection control, and standard precautions are implemented;

(17) That an effective disaster and emergency evacuation plan, with sufficient evacuation drills is in place;

(18) That an individual may not perform the duties of a paid staff person; and

(19) That an individual only perform those duties and tasks that are shared by the household or included as an activity documented in the individual's IP or remunerated as part of a training program as required by federal or State law.

B. A licensed community residential service provider offering services in alternative living units or group homes shall develop an emergency plan for all types of emergencies and disasters that shall include:

(1) Procedures that will be followed before, during, and after an emergency to address the following:

- (a) The evacuation, transportation, or 72 hour shelter-in-place of individuals and staff served;
  - (b) Holding an annual practice drill coordinated with local emergency planners for sheltering in place or evacuating;
  - (c) Preparing an after action report and improvement plan after drills that evaluates the plan and takes corrective actions;
  - (d) Ensuring that individuals served and staff have identification with current health, contact, and other important information that is immediately accessible in the event of evacuation;
  - (e) The role of the resident, family member, or legal representative in the event of evacuation;
  - (f) Arranging for medical needs and other accommodations for individuals served and staff at alternative facilities or shelters; and
  - (g) Establishing a communication protocol among all appropriate parties that includes redundant communication means;
- (2) The notification to families, staff, and the respective DDA regional office (licensing authority) regarding the action that will be taken concerning the safety and well-being of the individuals served;
- (3) The staff coverage, organization, and assignment of responsibilities that includes:
- (a) Planning staff coverage needs for ongoing shelter in place or evacuations;
  - (b) Identifying staff members available to report for work or remain during extended periods; and
  - (c) Establishing staff notification and recall contingency plans and procedures;
- (4) The continuity of operations, including, but not limited to, redundant communications systems, preservation of records and electronic data, the procurement of essential goods, equipment, and services, plans to secure vacated facilities, and the relocation to alternate facilities;
- (5) Procedures to:
- (a) Backup and electronically store off-site, appropriate records and data of consumers and staff and facility documents, for access under emergency conditions;
  - (b) Ensure access to an electronic copy of the emergency plans when requested by local, State, or federal emergency management organizations;

(6) Provisions to ensure that the facility's emergency and disaster plans are shared with local emergency management organizations for the purpose of coordinating local emergency planning; and

(7) An executive summary of the evacuation procedures that shall be provided to the family member of a resident on request.

C. The licensee shall ensure that all staff, care providers, consultants, and volunteers are aware of the policies required by this chapter and that all staff, care providers, consultants, and volunteers implement each policy as adopted.

D. The licensee shall ensure that it provides sufficient information about its grievance process to each individual it serves and, when appropriate, to the individual's proponent, to enable the individual or proponent to use the process effectively.

## 10.22.02.11

### **.11 Staffing Requirements.**

A. Following an analysis of the number of individuals the licensee intends to serve and the needs of each of these individuals being served, the licensee shall develop and implement a staffing plan that adequately addresses the health and safety needs of each individual and provides each individual with the services identified in the IP. The staffing plan may include any person who meets the training requirements of this regulation and who does not have a criminal history as set forth in §B of this regulation. A staff person who meets the above criteria may assume all responsibilities previously assigned to a qualified developmental disabilities professional.

B. A licensee may not employ or contract with any person who has a criminal history which would indicate behavior potentially harmful to individuals, documented through either a criminal history records check or a criminal background check, pursuant to Health-General Article, §19-1902 et seq., Annotated Code of Maryland, and COMAR 12.15.03.

C. The licensee shall develop and implement staff and care provider training and ensure through appropriate documentation that, before being assigned independent duties:

(1) All staff and care providers receive adequate training to perform their assigned duties;

(2) All staff and care providers successfully complete the Administration's approved training to meet the specific needs of the individuals they serve and to carry out their assigned duties, such as training in:

(a) Seizure disorders,

(b) Principles of behavior change,

(c) Management of disruptive behaviors,

(d) Medication administration, and

(e) The aging process and the special needs of the elderly; and

(3) All staff and care providers receive training in blood-borne pathogens in accordance with OSHA guidelines found in 29 CFR §1910.1030, which is incorporated by reference.

D. All staff and care providers shall receive Administration-approved training within 3 months of hire in the following:

(1) Community integration and inclusion,

(2) Individual-directed, outcome-oriented planning for individuals,

(3) General characteristics and needs of individuals served,

(4) First aid and cardiopulmonary resuscitation (CPR), based on the guidelines of the American Red Cross or another nationally recognized organization,

(5) Fundamental rights of individuals with developmental disabilities,

(6) Communicable diseases,

(7) Supporting individuals and families in making choices, and

(8) Communication skills.

E. A licensee shall develop and adopt:

(1) Written job descriptions that include the nature and extent of training and experience required for each position; and

(2) A policy to prevent employment discrimination.

10.22.02.12

## **.12 Health and Safety Requirements.**

A. To obtain and maintain licensure, a licensee shall ensure that any licensed home or site in which the licensee provides services to individuals:

(1) Meets local zoning requirements, except as otherwise set forth in Health-General Article, §7-603, Annotated Code of Maryland;

(2) Meets local and State building requirements;

(3) Meets applicable life safety requirements;

(4) Is free from safety and health hazards; and

(5) Is in good repair.

B. A licensee shall ensure that any licensed home or site in which the licensee provides services is free from fire hazards and has the following minimum fire safety protections:

(1) Adequate smoke detectors;

(2) Working and updated fire extinguishers; and

(3) A written fire evacuation plan, as required by Regulation .10A(17) of this chapter.

C. A licensee shall ensure that any licensed home or site in which the licensee provides services to individuals maintains its water temperature at a maximum of 110°F, unless:

(1) Each individual living in the home or receiving services at the site is capable of regulating water temperature safely; and

(2) There is documentation of the capability required in §C(1) of this regulation in each individual's IP.

D. In order to ensure the health and safety of individuals who require staff assistance in the administration of medication, the licensee shall:

(1) Require that all medication be administered in accordance with the Administration's curriculum on medication training;

(2) Provide oral, solid medications in a unit dose package unless an individual's IP indicates that this is not required;

(3) Provide medication for an individual who is absent from a program in a separate, pharmaceutically prepared package that is easily identified by the individual administering the medication; and

(4) Request, from the pharmacy, computer-generated medication administration records, treatment administration records, and physician medication order forms.



### **.13 Records.**

A. A licensee shall maintain records for each individual at the site where the individual is being served.

B. The records shall include at a minimum:

(1) The identifying information which appears on the individual's application for services from the Administration;

(2) Sufficient information that enables the licensee to provide services in a manner which ensures the individual's health and safety, including:

(a) An emergency contact person for the individual,

(b) The names of the individual's next of kin,

(c) The individual's physician,

(d) The individual's current diagnosis,

(e) Documented allergies of the individual, and

(f) A listing of the medications the individual receives;

(3) The IP as defined in COMAR 10.22.05;

(4) Documentation demonstrating implementation of the IP; and

(5) Any other information the Administration may require.

C. On notification of a medical emergency, the licensee shall ensure that the individual's medical information is available and readily accessible to emergency personnel.

D. The licensee shall:

(1) Maintain an individual's records for a minimum of 5 years, regardless of whether the individual is no longer being served or dies;

(2) Maintain documents relevant to the services the individual is currently receiving, as long as the individual is being served; and

(3) Organize an individual's record in a manner that facilitates easy access to needed information.

#### **.14 Quality Assurance.**

A. The licensee shall submit a quality assurance plan and any subsequent substantive changes to the plan to the Administration for approval.

B. The licensee shall develop and implement a system of internal quality assurance which at a minimum:

- (1) Is focused on the individual's choices, preferences, and satisfaction, and includes personal contact with the individuals being served;
- (2) Has outcomes and results that are measurable and may be incorporated into future IPs for the individuals being served;
- (3) Has outcomes and results that are measurable and may be incorporated into systemic changes in a licensee's operation;
- (4) Collects and evaluates data and analyzes trends identified through quality assurance activities including:
  - (a) The name of the individual with a behavior plan,
  - (b) The medication or other restrictive technique used,
  - (c) The date and time the restrictive technique was used,
  - (d) Whether the medication or other restrictive technique was used as an emergency or as part of a behavior plan, and
  - (e) Whether the medication or other restrictive technique used is meeting the goals and objectives established in the behavior plan;
- (5) Provides for prompt and appropriate response when an individual's health or safety is at risk; and
- (6) Includes proactive strategies to improve the quality of services, including health and safety.

C. The licensee shall:

- (1) Establish goals and standards to measure the quality of services being delivered and define how the standards are measured;

- (2) Maintain records to demonstrate the effectiveness of its quality assurance activities;
- (3) Implement changes based on the results of the evaluated data; and
- (4) Be held accountable by the Administration for accomplishing the goals and standards that are established as part of the licensee's system of quality assurance.

D. The Administration may request documentation from a licensee to verify that the licensee is accomplishing the goals and standards set forth in the licensee's quality assurance plan.

E. Standing Committees.

(1) The licensee shall establish a committee or committees to perform the following functions:

- (a) Perform the quality assurance functions set forth in this regulation;
- (b) Review the licensee's protocol for identifying, reporting, documenting, investigating, and reviewing of incidents to ensure compliance with Administration procedures;
- (c) Monitor whether the licensee's protocol identified in §E(2) of this regulation is being properly implemented by reviewing all incidents in an effort to identify deficient practices and recommend necessary corrective action;
- (d) Approve all behavior plans which use restrictive techniques to ensure that the behavior plan complies with the requirements of COMAR 10.22.04.03A and 10.22.10;
- (e) Review, approve, and establish the time frame for the restriction of a right if it is not related to a challenging behavior, in accordance with COMAR 10.22.04.03A; and
- (f) Review the licensee's policies and procedures, and implementation of them, to ensure that they adequately protect the legal and human rights of each individual served by the licensee.

(2) The committee or committees may be organized to perform the functions set forth in §A of this regulation for one or more licensees.

(3) The committee or committees shall include an equal number of licensee staff, and individuals, proponents, or members of the community who are not employed by the licensee. For a committee member who is remunerated only to serve as a member of the committee, that member is not counted as staff or as a member of the community.

(4) The committee or committees may consult with a licensed health professional such as a psychologist, physician, physician's assistant, nurse practitioner, or board-certified clinical pharmacist, as needed.

(5) A committee member may not participate in the decision making process of any:

- (a) Incident in which the committee member was involved; or
- (b) Behavior plan the committee member has developed.
- (6) The committee or committees shall meet as needed to perform the functions identified in §E(1) of this regulation, with, at least, a majority of members present.
- (7) The committee or committees shall ensure confidentiality for the individual in accordance with Health-General Article, §7-1010, Annotated Code of Maryland.

10.22.02.9999

### Administrative History

*Effective date: July 26, 1999 (26:15 Md. R. 1148)*

Regulation .01 amended and recodified to be Regulation .01-1 and new Regulation .01 adopted effective May 5, 2008 (35:9 Md. R. 897)

Regulation .02A, D amended effective January 2, 2006 (32:26 Md. R. 1997)

Regulation .02A amended as an emergency provision effective July 10, 2008 (35:16 Md. R. 1388); emergency status extended to at 36:2 Md. R. 96; amended permanently effective January 26, 2009 (36:2 Md. R. 100)

Regulation .03 amended effective May 5, 2008 (35:9 Md. R. 897)

Regulation .04 amended effective January 2, 2006 (32:26 Md. R. 1997)

Regulation .05B amended effective January 2, 2006 (32:26 Md. R. 1997)

Regulation .08B, C amended effective January 2, 2006 (32:26 Md. R. 1997)

Regulation .08B, C amended as an emergency provision effective July 10, 2008 (35:16 Md. R. 1388); emergency status extended at 36:2 Md. R. 96; amended permanently effective January 26, 2009 (36:2 Md. R. 100)

Regulation .10 amended effective December 17, 2007 (34:25 Md. R. 2210)